UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,903	02/28/2007	Tracey Jean Brown	650064.407USPC	7122

500 7590 08/19/2008

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,903	BROWN ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *3-10 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 are pending.

Election/Restrictions

2. Applicant's election of Group 5, drawn to an isolated compound wherein the compound is an antibody that specifically targets SEQ ID NO: 25 in the reply filed on 06/03/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, claims 1 and 2 have been rejoined with Group 5 to the extend that they read on the elected Invention drawn to the antibody.

Claims 3-10 and 14-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions/species, there being no allowable generic or linking claim.

Claims 1-2 and 11-13 are currently under examination as they read on the elected invention drawn to an isolated compound wherein the compound is an antibody that specifically targets SEQ ID NO: 25 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 25.

Applicant is invited to amend the claims to recite "antibody" in place of "compound".

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Foreign priority applications, 2003905551 and 20033906658, appear to provide sufficient written support for claims 11-13.

Specification

4. Applicant is requested to review the application for spelling error, the use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Claim Rejections - 35 USC § 112 second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 12 is indefinite in the recitation of "deimmunized antibody". The specification provides the following description for "deimmunized antibody":

> The present invention provides, therefore, interactive molecules such as but not limited to antibodies and other immunoglobulins including fragments, derivatives, antigen binding portions, recombinant forms, chimeric forms as well as **deimmunized** including humanized forms thereof directed to the subject modulators and small molecule inhibitors. (page 26, lines 26-30)

> The antibodies may also be humanized or chimeric or are human antibodies suitable for administration to humans. These include humanized antibodies prepared, for example, from murine monoclonal antibodies, and human monoclonal antibodies which may be prepared, for example, using transgenic mice as described below, or by phage display. A "humanized" antibody includes a **deimmunized antibody**. (page 27, lines 9-13)

Besides these two instances, the specification does not appear to provide a definition for “deimmunized antibody”. In view of the above description for the “deimmunized antibody”, it is unclear how a humanized antibody is distinct from a deimmunized antibody as recited in the markush group in claim 12. Therefore, the metes and bounds of the claim is ambiguous and ill-defined.

For examination purposes, the “deimmunized antibody” reads on a humanized antibody.

B) Claims 11-13 are indefinite in the recitation of “or otherwise associating with HAS”. The specification does not provide any other form of “association with HAS” other than the antibody binding to HAS. Therefore, one of skill in the art is not reasonably apprised of the metes and bounds of the "otherwise association" with HAS. As such the claim is indefinite.

C) Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-2 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"**Interactive molecule**" (claims 11-13)

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C § 112, paragraph 1 "Written Description" requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by **disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure**, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January, 2001, See especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the genus of "*interactive molecules capable of binding or otherwise associating with HAS to reduce HAS function or activity*".

The instant specification provides the following description for "interactive molecules"

> The present invention is directed to compounds, such as nucleic acid and nucleic acid-like oligomer compounds or complexes comprising same, which are targeted to a nucleic acid encoding HAS and/or HYAL a nucleic acid molecule required for or which facilitates expression of HAS and/or HYAL-encoding material as well as compounds such as **interactive molecules including antibodies or recombinant or chimeric or derivative forms thereof or small molecules which are specific for HAS and/or HYAL and which antagonize HAS and/or HYAL function or activity**. (page 3)

The claimed "interactive molecule" is not limited to antibody as applicant intended but do not require that all "**interactive molecules**" to share the binding capability to HAS in the absence of sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics. Therefore, the claimed invention is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the all the "**interactive molecules**" capable of binding or otherwise associating with HAS to reduce HAS function or activity.

Applicant is invited to amend the claims to recite "antibody" instead of "**interactive molecule**" in order to obviate this rejection.

"conservative amino acid substitution" (claims 1-2 and 11-13)

As the instant claims are directed to an antibody that binds a sequence containing one or more conservative amino acid substitutions, Applicant has not provided a sufficient written description of such antibody that selectively binds to such variant sequences, because such antibody would not reasonably be expected to be reactive with all the species of the sequences with the conservative amino acid substitutions. For example, Lederman et al. (*Molecular Immunology* 28: 1171-1181, 1991; see entire document) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody. Further, Li et al. (*PNAS* 77: 3211-3214, 1980; see entire document) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document). Therefore, the specification does not provide for sufficient written description to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, Applicant had possession of antibodies reactive with all the sequences of SEQ ID NO: 25 with conservative amino acid substitutions.

Applicant is invited to amend the claims to delete the recitation of "**conservative amino acid substitution**" in order to obviate this rejection.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co*. 43 USPQ2d 1398.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2 and 11-13 is rejected under 35 U.S.C. 102(b) as being anticipated by Briskin et al. (US 20020151026 A1, see entire document).

Briskin et al. teach an antibody that binds and inhibits HAS comprising the sequence of SEQ ID NO: 25 (see figures 2, amino acid residues corresponding to nucleic acids 1577-1600; paragraphs [0062]-[0068]; and claims 13-14). In addition, Briskin also teaches the antigen-binding fragments of the antibody (see paragraph [0008]).

Briskin et al. does not teach the antibody to target the specific sequence of SEQ ID NO: 25, however, given that the recitation of "one or more conservative amino acid substitutions" does not limit the antigen specificity of the antibody to be SEQ ID NO: 25, under the broadest reasonable interpretation of the claim, Briskin's antibody that binds HAS meets the present claim. In addition, it is noted that the transitional phrase in the recitation of "a sequence containing one or more conservative amino acid substitutions" is open. Therefore, the sequence is not limited to SEQ ID NO: 25.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-2 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briskin et al. (US 20020151026 A1) in view of Falkenberg et al. (*J. Clin. Chem. Clin. Biochem*. 1984, 22:867-882) and Owens et al. (*Journal of Immunological Methods*, 1994, 168:149-165).

The teaching of Briskin et al. has been discussed above. Briskin et al. do not teach the antibody to be monoclonal, polyclonal or a humanized antibody.

With regard to humanized antibody the following is noted:

As noted above in section under 35 USC 112 second paragraph, "immunized antibody" reads on a humanized antibody.

Although Briskin does not teach the antibody to be humanized or an antigen-binding fragment thereof, it would have been obvious to one of skill in the art at the time of the invention was made to generate humanized antibodies against HAS because it is well-known in the art to make humanized antibodies as evidenced by Owens et al.

In particular, Owens et al. teach the methods of humanizing rodent monoclonal antibodies by making human chimeric and human CDR-grafted antibodies from rodent monoclonal antibodies (see pages150-155).

One of ordinary skill in the art would have been motivated to make a chimeric, humanized antibody against the polypeptide taught by Briskin et al. because the antibody can be used for in vivo diagnosis and therapeutic purpose as taught by Briskin (see paragraphs [0062]-[0070]) and that making a humanized antibody is advantageous to the rodent monoclonal antibody for human diagnosis or therapy as taught by Owens (see Introduction).

Given that Briskin teaches a monoclonal antibody that binds to the HAS of the present invention and that Briskin teaches the antibody can be used for therapy and diagnosis; in view the well-known technology of making humanized antibody from a rodent monoclonal antibody as taught by Owens and that it would be advantageous to have humanized antibodies than the rodent monoclonal antibody for human diagnosis or therapy as taught by Owens, it would have *prima facie* obvious to one of ordinary skill in the art to make an antibody that binds the HAS of the present invention wherein the antibody is humanized.

With regard to the monoclonal and polyclonal antibodies, the following is noted:

The Briskin reference has been discussed above.

The Briskin reference differs from the present claims in that it does not teach the antibody to be monoclonal or polyclonal.

However, it was well known in the art at the time of the invention was made to produce a polyclonal antibody as evidenced by Falkenberg by stating that "[c]onventionally prepared antibodies have been used for many decades in biology and medicine for research as well as for diagnostic and therapeutic purposes" (see page 868, right column, last paragraph).

In addition, Falkenberg et al. teach production of monoclonal antibodies using hybridomas, a techniques well known in the art at the time the invention was made (e.g., see page 869 "The Hybridoma Technology").

Falkenberg et al. compare monoclonal antibodies and polyclonal antibodies and conclude that monoclonal antibodies are advantageous over conventional antisera when the two antibody sources are compared (e.g., see page 872, "Application of Monoclonal Antibodies Instead of Conventional Sera"). In particular Falkenberg et al. notes that the hybridomas are immortal and capable of unlimited growth and production of unlimited antibody (e.g., see page 869 "The Hybridoma Technology").

Given the teaching by Briskin et al. in that antibody was used in immunoassays such as ELISA blot (see paragraph [0066]), it would have been obvious to the ordinary artisan to use a polyclonal or a monoclonal antibody in the assays as taught by Briskin et al. because polyclonal antibodies have been used for decades for diagnostic purposes; while on the other hand, hybridomas are capable of unlimited production of monoclonal antibody.

One of ordinary skill in the art would have been motivated to use a hybridoma to produce monoclonal antibodies for its high specificity in an immunodetection assay because Briskin et al teach that the antibody is useful for immunodetection assays, such as ELISA.

Given the above discussion, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Sharon Wen, Ph.D.
Examiner, Art Unit 1644
August 14, 2008

/Phillip Gambel/
Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
Art Unit 1644
August 18, 2008